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ERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

rnational Patent Classification 5 : IB 17/00	A1	(11) International Publication Number: WO 94/28800 (43) International Publication Date: 22 December 1994 (22.12.94)

rnational Application Number: PCT/US94/06324

rnational Filing Date: 3 June 1994 (03.06.94)

rity Data:
8/072,293 4 June 1993 (04.06.93) US

(81) Designated States: AU, BB, BG, BR, BY, CA, CN, CZ, FI, GE, HU, JP, KG, KP, KR, KZ, LK, LV, MD, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SI, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

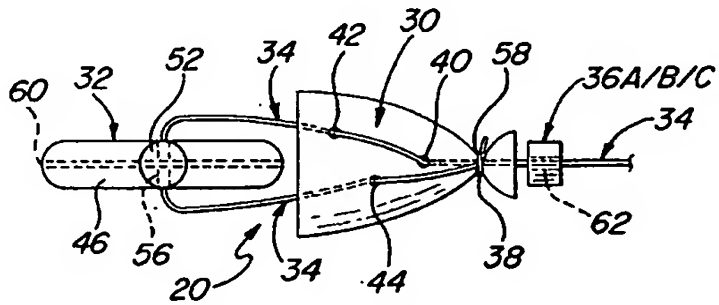
Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

licant: KENSEY NASH CORPORATION [US/US]; Marsh Creek Corporate Center, Suite 204, 55 East Uwchlan Avenue, Exton, PA 18976 (US).

utors: NASH, John; 145 Oak Street, Downingtown, PA 9335 (US). EVANS, Douglas; 305 Dorset Road, Devon, A 19333 (US).

t: FAIGUS, Martin, L.; Caesar, Rivise, Bernstein, Cohen Pokotilow, Ltd., Seven Penn Center, 12th floor, 1635 Market Street, Philadelphia, PA 19103-2212 (US).

: HEMOSTATIC VESSEL PUNCTURE CLOSURE WITH FILAMENT LOCK



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emostatic closure (20, 100) for sealing a percutaneous puncture (24A, 24B) in a blood vessel (22). The puncture includes a) leading to it from the skin of the being. The closure (20, 100) comprises a rigid, resorbable material anchor (32) having a ent strip (60) therein, a compressed collagen plug (30), a thin filament (34, 34') connecting the anchor (32) and the plug (30) in ike arrangement, and a locking mechanism (36 A/B/C, 56'). The plug (30) is deployed so that the anchor (32) is pulled against contiguous with the puncture (24B) inside the artery (22) and with the plug (30) within the puncture tract. Pulling on the filament moves the plug (30) toward the anchor member (32) to a puncture sealing position. The locking mechanism (36 A/B/C, 56') is to be actuated to engage the filament (34, 34') in such a manner that the plug is held in the puncture sealing position. In one nt the locking mechanism comprises a compressible disk (36 A/B/C) mounted on the filament and located within the puncture another embodiment the locking mechanism comprises a notched passageway (56') in the anchor (32) and the filament (34') a portion having plural projections (102) or teeth thereon adapted to slide into the notched passageway (56') in one direction but

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HEMOSTATIC VESSEL PUNCTURE CLOSURE WITH FILAMENT LOCK

BACKGROUND OF THE INVENTION

This invention relates generally to medical devices and ıore particularly to hemostatic closures for sealing percutaneous .ncisions or punctures in blood vessels or other body vessels, lucts, or lumens.

In United States Letters Patent No. 5,021,059, which ıas been assigned to the same assignee as this invention, and /hose disclosure is incorporated by reference herein, there is lisclosed a closure device and method of use for sealing a small .ncision or puncture in tissue separating one portion of the body ıf a living being from another portion thereof, e.g., a percutan- ;ous puncture in an artery, to prevent the flow of a body fluid, :.g., blood, through the puncture. The closure device is rranged to be used with (deployed by) an instrument which omprises a carrier in the form of a tubular member. The tubular ember has a proximally located portion and a distally located ortion. The latter includes an open free end arranged to be ntroduced through the incision or puncture. The proximately ocated portion of the tubular member is arranged to be located ut of the body of the being when the distally located portion s extended through the incision or puncture.

The closure device comprises three components, namely, n anchor member, a sealing member, and a filament, e.g., suture. he anchor member includes a tissue engaging portion configured o pass through the puncture in one direction but resistant to assage therethrough in the opposite direction. The sealing ember is formed of a hemostatic material, such as compressed ollagen foam, and has a tissue engaging portion. The filament s connected between the anchor member and the sealing member in pulley-like arrangement so that they may be moved relative to ach other by the application of a pulling force on the filament.

The instrument is arranged to expel the anchor member hrough the puncture, e.g., into the artery, and to draw its issue engaging portion into engagement with the tissue ontiguous with the puncture. The filament extends through the nstrument to a point outside the body of the being and is rranged to be drawn in the proximal direction, whereupon the

portion of the filament connecting the anchor member causes the tissue engaging portion of the sealing member to move with respect to the anchor member, thereby drawing the anchor member and sealing member together. This action causes the tissue engagement portion of the sealing member to seal the puncture from the flow of fluid therethrough.

In a copending United States Patent Application Serial No. 07/846,322, filed on March 5, 1992, entitled Hemostatic Puncture Closure System and Method of Use, which is a Continuation-In-Part of a copending United States Patent Application Serial No. 07/789,704, filed on November 8, 1991, and of the same title, both of which are assigned to the same assignee as this invention, and whose disclosures are also incorporated by reference herein, there are disclosed variant systems for sealing a percutaneous incision or puncture in a blood vessel. Those systems basically comprise a closure, an introducer, and a deployment instrument including a carrier for the closure.

The closure has three basic components, namely, a sealing member, an intraarterial anchor member, and a positioning member. The sealing member is in the form of an elongated rod-like plug, e.g., a compressed hemostatic, resorbable collagen sponge or foam. This plug member is arranged for sealing the puncture. The anchor member is an elongated, stiff, low-profile member which is arranged to be seated inside the artery against the artery wall contiguous with the puncture. The anchor member is molded of non-hemostatic resorbable polymer similar to resorbable suture. The positioning member comprises a filament, e.g., a resorbable suture. The filament connects the anchor member and the collagen plug (sealing member) via a pulley-like arrangement which serves to move the plug toward the anchor member by pulling on the filament when that member is located within the interior of the artery and in engagement with the inner wall of the artery contiguous with the incision or puncture. A tamping member, forming a portion of the deployment instrument is provided to tamp the plug within the puncture tract. This action causes the plug to deform so that its

liameter increases somewhat. Expansion of the plug is enhanced)y the fact that it is formed of a compressed collagen so that it expands in the presence of blood within the puncture tract. The expansion of the plug within the puncture tract serves to iold it in place. The closure quickly becomes locked in place :hrough the clotting of the hemostatic collagen plug within the)uncture tract, and by tension applied to the filament via spring ieans forming a portion of the deployment system.

In another copending United States Patent Application ierial No. 08/012,816, filed on February 3, 1993, entitled A lemostatic Vessel Puncture Closure System Utilizing A Plug ocated Within The Puncture Tract Spaced From The Vessel, And lethod Of Use, which is assigned to the same assignee as this nvention, and whose disclosure is also incorporated by reference ierein, there is disclosed a system for sealing a percutaneous ncision or puncture in a blood vessel or other lumen. That ystem includes a closure, similar in most respects to the losures disclosed in the above mentioned copending application ut also having means for preventing the sealing portion of the losure from gaining access into the interior of the artery. In articular, the closure of that application includes a spacer ember interposed between the anchor member and the plug member o keep the plug member in the puncture tract, but spaced from he opening in the artery.

In yet another copending United States Patent pplication Serial No. 08/064,192, filed on May 17, 1992, ntitled Fail Predictable, Reinforced Anchor For A Hemostatic uncture Closure, which is also assigned to the same assignee as his invention, and whose disclosure is also incorporated by eference herein, there is disclosed another closure for sealing percutaneous puncture in a blood vessel. That closure is imilar in construction to the closures of the above mentioned pplications except that its anchoring means comprises a enerally elongated member formed of a resorbable material having einforcing means, e.g., a filament, ribbon or mesh also formed f a resorbable material, extending along substantially the ength thereof and fixedly secured thereto, e.g., molded in situ

therein. The reinforcing means prevents the anchoring member from breaking apart and separating from the closure in the event of a failure in the closure or an incorrect deployment.

While the closures of the aforementioned patent applications are suitable for their intended purposes, they still may leave something to be desired from the standpoint of resistance to relative movement between the sealing member and the anchor member until the puncture is sealed and the closure locked in place through the clotting of the hemostatic collagen plug within the puncture tract.

OBJECTS OF THE INVENTION

Accordingly, it is a general object of this invention to provide a closure device and methods of use for sealing a percutaneous puncture in a vessel, duct, or lumen, and which overcomes the disadvantages of the prior art.

It is a further object of this invention to provide a vessel puncture closure device including an anchoring portion located within the vessel and an sealing portion located within the puncture tract and means for ensuring that the sealing portion and anchoring portion do not move relative to each other once properly positioned in order to facilitate the vessel sealing operation.

It is still a further object of this invention to provide a vessel puncture closure device which is simple in construction, easy to use, safe, effective, and reliable.

SUMMARY OF THE INVENTION

These and other objects of this invention are achieved by providing a closure device for sealing a percutaneous incision or puncture in a vessel, duct or lumen. The puncture comprises a tract extending through tissue overlying the opening in the vessel. The closure device comprises a anchoring means, sealing means, filament means, and a locking means.

The anchoring means is arranged to be brought into engagement with the interior tissue of the vessel contiguous with the opening in the vessel and with the sealing means being located within the puncture tract remote from the vessel. The filament means is connected between the anchoring means and the

sealing means so that the sealing means may be moved in the tract toward the anchoring means to a puncture sealing position by the application of a pulling force on the filament means. The anchoring means is in engagement with the interior tissue of the vessel contiguous with the opening therein when the sealing means is in the puncture sealing position.

The locking means is actuatable to cooperate with the filament means to hold the anchoring means and the sealing means in the puncture sealing position.

In accordance with one aspect of this invention the locking means comprises a member slidably disposed on the filament means and arranged to be actuated by the application of a compressive axial force onto it to cause it to collapse radially to frictionally engage the filament means to prevent the sealing means and the anchoring means from moving relative to each other.

In accordance with another aspect of this invention the locking means comprises a filament engagement portion configured to enable the filament means to be slid with respect to the anchoring means and the sealing means in a first direction, but precluded from sliding with respect to the anchoring means and the sealing means in a second, opposite direction. In accordance with that aspect of the invention the filament means comprises a plurality of projections extending along at least a portion of the length of the filament means. The filament engagement portion of the locking means comprises a passageway in the anchoring means having at least one notch therein to receive one of the projections, with the notch being configured to enable the projections to slide therein from the first direction, but preventing any projection from sliding thereout in the second direction.

In accordance with another aspect of this invention the closure may include a spacer interposed between the anchor member and the sealing member to prohibit the sealing member from contacting the vessel wall and thereby possibly entering into the vessel where a portion could conceivably break off and flow distally and create an embolism.

DESCRIPTION OF THE DRAWINGS

Other objects and many of the attendant advantages of his invention will readily be appreciated as the same becomes etter understood by reference to the following detailed escription when considered in connection with the accompanying rawings wherein:

Fig. 1 is a top plan view of one embodiment of the losure device of this invention, with the sealing component of he device shown in its uncompressed state;

Fig. 2 is a side elevational view, partially in ection, showing a portion of the deploying instrument and the losure device of Fig. 1, but with the sealing component of the losure device in its compressed state;

Fig. 3 is an illustration showing the closure device f Fig. 1 in place after it has sealed the percutaneous puncture n an artery;

Fig. 4 is a top plan view of a second embodiment of the losure device of this invention, with the sealing component of he device shown in its uncompressed state;

Fig. 5 is a side elevational view, partially in ection, showing a portion of the deploying instrument and the losure device of Fig. 4, but with the sealing component of the losure device in its compressed state;

Fig. 6 is an illustration showing the closure device f Fig. 4 in place after it has sealed the percutaneous puncture n an artery;

Fig. 7 is a top plan view of a third embodiment of the losure device of this invention, with the sealing component of he device shown in its uncompressed state;

Fig. 8 is a side elevational view, partially in ection, showing a portion of the deploying instrument and the losure device of Fig. 7, but with the sealing component of the losure device in its compressed state;

Fig. 9 is an illustration showing the closure device f Fig. 7 in place after it has sealed the percutaneous puncture n an artery;

Fig. 10 is an enlarged top plan view of one embodiment of the locking component of the closure devices of Figs. 1, 4, and 7;

Fig. 11 is a sectional view taken along line 11 - 11 of Fig. 10;

Fig. 12 is a sectional view similar to that of Fig. 11 but showing the locking component of Fig. 10 after it has been operated to prevent the sealing component and the locking component from moving relative to each other;

Fig. 13 is an enlarged top plan view of a second embodiment of the locking component of the closure devices of Figs. 1, 4, and 7;

Fig. 14 is a sectional view taken along line 14 - 14 of Fig. 13;

Fig. 15 is a sectional view similar to that of Fig. 14 but showing the locking component of Fig. 13 after it has been operated to prevent the sealing component and the locking component from moving relative to each other;

Fig. 16 is an enlarged top plan view of a third embodiment of the locking component of the closure devices of Figs. 1, 4, and 7;

Fig. 17 is a sectional view taken along line 17 - 17 of Fig. 16;

Fig. 18 is a sectional view similar to that of Fig. 17 but showing the locking component of Fig. 16 after it has been operated to prevent the sealing component and the locking component from moving relative to each other; and

Fig. 19 is an enlarged illustration showing a fourth embodiment of closure device, partially in section, in place after it has sealed the percutaneous puncture in an artery and showing the cooperation of its locking means and the filament component of that closure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 a closure device constructed in accordance with one embodiment of this invention, to seal a

percutaneous puncture within a blood vessel 22, e.g., the femoral artery. The puncture includes the tract 24A leading up to the opening 24B in the wall of the vessel. By tract it is meant the passageway in the tissue located between the vessel and the skin of the being formed when the vessel is punctured.

The embodiment of the closure 20 shown in Fig. 1 has four basic components, namely, a sealing member 30, an intraarterial anchor member 32, a positioning filament 34, and a locking member 36. Except for the locking member 36, and some aspects of the anchor member 32, the closure 20 is constructed in accordance with the teachings of the aforementioned patent applications. Thus, the sealing member or plug 30 comprises a cylindrical member formed of a compressible, resorbable, collagen foam, which is arranged to be compressed from the large diameter configuration shown in Fig. 1 to the small diameter, elongated configuration shown in Fig. 2. In the configuration of Fig. 2 the diameter of the plug is very small, e.g., 1.32 mm, and therefor suitable for disposition within a deployment instrument 0 (Figs. 2, 5, and 8) constructed in accordance with the teachings of the aforementioned applications. The plug 30 includes an annular recess 38 extending about its outer periphery adjacent its proximal end. Three apertures 40, 42, and 44 extend through the plug. In particular, the aperture 40 is located close to the recess 38 and diametrically through the centerline of the plug. The aperture 42 is located close to the distal end of the plug and extends transversely through the plug on one side of the centerline. The aperture 44 is located between apertures 0 and 42 and extends transversely through the plug on the other side of the centerline. These apertures serve as passageways through which the positioning filament 34 extends to connect the anchor member 32 to the plug 30.

The anchor member 32 basically comprises a thin, narrow, strip or bar of material which is preferably constructed in accordance with the teachings of the above described patent application S.N. 08/064,192, filed on May 17, 1993, and entitled Fail Predictable, Reinforced Anchor For A Hemostatic Puncture Closure. The strip is sufficiently rigid such that once it is

n position within the artery or other vessel, duct, or lumen, t is resistant to deformation to preclude it from bending to ass back through the puncture through which it was first ntroduced. The anchor member 32 has a generally planar top urface 46, a radially contoured bottom surface 48, and a eripheral side surface 50. Each end of the member 32 is ounded. The side surface 50 of the anchor member 32 tapers nward slightly from its top surface 46 to its bottom surface 48 s shown in Fig. 2 to facilitate the removal of the plug from the old for making it. A hemispherical dome-like projection 52 is ocated at the center of the top surface. The top of the rojection 54 is slightly flat. The dome-like projection 52 is rranged to extend into the opening 24B in the blood vessel wall hen the anchor member 34 is properly deployed within that essel.

A passageway 56 of generally square profile and rounded orners extends transversely across the member 32 below the rojection 52 and close to the bottom surface 48. The filament 4 is threaded through the passageway 56 as shown clearly in igs. 1 and 2 to connect the plug member 30 to the anchor member 2 in a pulley-like arrangement for effecting the movement of the lug component toward the anchor component once the anchor omponent is in its desired position in the vessel. In articular, the pulley-like connection between the anchor member nd the plug member is accomplished by threading the filament 34 rom a remote, externally located point into a passageway in the lug through the apertures 40 and 42 and out of the distal end f the plug and into the transversely extending passageway 56 on ide of the anchor member, through that passageway to the pposite side of the anchor member (the side close to the top of he page in Fig. 1), and from there back into the plug, where it s threaded out through the aperture 44 to the opposite side of he plug, where it terminates in a loop 58 (Fig. 3) extending round the annular recess 38. The loop is secured by a knot 58A.

In order to ensure that no portion of the anchor member an break off and separate from the closure 20 when the anchor ember 32 is deployed within the blood vessel, the anchor member

includes a flexible strip 60, e.g., a resorbable suture, serving as reinforcing means. The strip 60 extends along the length of the elongated portion of the anchor and is fixedly secured, e.g., molded in situ, within the elongated portion of the anchor member just under the top surface 46 and above the transversely extending passageway 56.

The locking member 36 basically comprises a disk-like or washer-like member, preferably formed of a resorbable material, such as that forming the anchor member, so long as it is somewhat deformable, as will be described later. The locking member has a central passageway 62 (Fig. 1) extending therethrough and through which a proximal portion of the filament 34 extends. In the embodiment of Fig. 1 the locking member 36 is located proximally of the sealing plug 30, with a proximal portion of the positioning filament 34 passing through its central passageway 62.

The internal diameter of the central passageway 62 is larger than the external diameter of the filament 34 to enable the filament to slide with respect thereto. The locking member 36 can take any form, providing that it is constructed so that upon the application of an axial compressive force thereon a portion of it is compressed radially inward to close the passageway 62 about the filament extending therethrough, thereby frictionally engaging that filament to preclude relative movement between the locking member and the filament. In Figs. 10 - 18 three suitable embodiments for the locking means are shown.

In particular, in Figs. 10 - 12 there is shown a locking member 36A in the form of a washer having one end in the form of a tapering cone 64, with the passageway 62 extending through the washer tapering as it passes through the cone end. In this embodiment an axial compressive force, i.e., a compressive force applied parallel to the longitudinal axis of the filament 34 passing through the locking member 36A, will cause the member to deform, like shown in Fig. 12, whereupon the conical end 66 of the passageway 62 will be collapsed inward radially so that the filament will be tightly grasped to prevent relative movement between it and the locking member.

In Figs. 13 - 15 there is shown a locking member 36B n the form of a washer having an annular tapering recess 68 xtending about the outer periphery of the member at pproximately the middle thereof. A central passageway 62 xtends through the member 36B. In this embodiment an axial ompressive force will cause the member to deform, like shown in ig. 15, whereupon the center 70 of the passageway 62 will be ollapsed inward radially so that the filament 34 will be tightly rasped to prevent relative movement between it and the locking ember.

In Figs. 16 - 18 there is shown a locking member 36C n the form of a pair of washers 36C' and 36C". Each of the ashers has a central passageway 62 extending therethrough. One nd of each of the washers 36C' and 36C" has a conical central esa 72 through which the passageway 62 extends. The portion 74 f the passageway extending through the mesa 72 is of a reduced iameter. The washers 36C' and 36C" are disposed so that their esas 72 are disposed opposite each other, and with central assageways 62 axially aligned so that the filament 34 extends herethrough. In this embodiment an axial compressive force pplied to the washers will cause each of them to deform, like hown in Fig. 18, whereupon the portions 74 of their passageways xtending through their mesas will be collapsed inward radially t 76 so that the filament will be tightly grasped to prevent elative movement between it and the locking washers.

The closure device 20 of this invention is used in the ame general manner as described in the foregoing patent pplications. In particular, the physician inserts the delivery r deployment instrument 10 containing the closure into the atients' introducer sheath (not shown). On insertion, the nchor member 32 passes out of the distal end of the introducer heath (like shown in Fig. 2) and deploys into the interior of he vessel, e.g., artery. The deployment instrument is then ithdrawn from the introducer sheath until resistance is felt hen the anchor member catches on the distal end of the ntroducer sheath. Once this occurs (and assuming that the nchor is in the correct orientation when it catches on the end

of the introducer sheath) the deployment instrument and the introducer sheath are then immediately withdrawn together. This withdrawing action causes the anchor member 32 to engage (catch) on the inside of the artery contiguous with the puncture 24B in the artery wall, with the domed portion 52 of the anchor member 32 extending through the puncture 24B. The continued simultaneous retraction of the introducer sheath and the deployment instrument causes the filament 34 to pull the collagen plug 30, and the locking member 36 out of the deployment instrument 10 and into the puncture tract 24A in that order.

Further, simultaneous retraction of the introducer sheath and the deployment instrument 10 brings an elongated clamping member (not shown) out of the free end of the deployment instrument. Moreover, the pulley arrangement of the filament 34 connecting the anchor member and the plug member ensures that during the retraction of the introducer sheath and the instrument, the plug member 30 is moved toward the anchor member until it engages the domed portion 52 of the anchor member 32 (which domed portion extends through the opening in the vessel wall as shown in Fig. 3). This action ensures that the plug member 30 is held away from the artery wall 22, thereby preventing any portion of the collagen plug member 30 which might break off from gaining ingress into the artery, where it could flow distally and form an embolism. Moreover, once the plug member engages the flat top of the domed portion 52 of the anchor continued retraction of the introducer sheath and deployment instrument causes the filament 34 to deform the plug 30 somewhat, i.e., causing it to deform radially outward. The existence of blood within the puncture tract 24A further contributes to the deformation of the plug member 30 since the collagen foam expands in the presence of blood.

The retraction procedure continues to pull the introducer sleeve and deployment instrument up the filament until a tag (not shown) fixedly secured onto a proximal portion of the filament is exposed. At this point the anchor member 32, the collagen plug member 30, and the locking member 36 will have been deployed, with the locking member located within the puncture

tract immediately proximally of the plug 30. The plug 30 is then tamped by a tamping member (not shown) forming a portion of the deployment instrument. In particular, the user quickly compacts the collagen of the plug by gently tensioning the filament by pulling on the introducer sheath and instrument 10 in the proximal direction with one hand. The tamping member is then manually slid down the filament by the user's other hand so that it enters the puncture tract 24A and engages the proximal end of locking member 38 to cause it to slide distally into the plug member 30 to compress the plug member. A few gentle compactions are adequate to achieve the desired result, i.e., to assist the plug member 30 in spreading out and conforming to the tract 24A, thereby assisting in holding the plug in place until hemostasis occurs (which happens very quickly).

After the tamping action is completed a torsion spring (not shown) is mounted on the filament 34 between the tag and the proximal end of the tamping member. This action is necessary to maintain appropriate tension on the filament 34 while the instrument 10 is removed (i.e., the filament 34 severed). The torsion spring places continuous tension on the filament 34 and continuous compression on the tamping member. Because the locking washer 36 is located between the plug 30 and the tamping member, the washer experiences an axial compressive force, thereby compressing it and causing it to frictionally engage or lock onto the filament. This action locks the closure 20 in position so that when the deforming load, e.g., the torsion spring, is removed the closure remains in position, i.e., the plug member 30 does not move away from the anchor member 32.

The closure 20 is also locked in place by virtue of the clotting of the hemostatic collagen plug. In this regard within a few hours after deployment, the anchor member 32 will be coated with fibrin and thus attached firmly to the arterial wall, thereby eliminating the possibility of distal embolization. After approximately thirty days, only a small deposit of anchor material will remain. In fact, resorption of all components will have occurred after approximately sixty days. Moreover, since the plug 30 is formed of compressed collagen or other hydrophilic

material it also expands automatically in the presence of blood within the puncture tract 24A when deployed, thereby further contributing to the plug's enlargement.

In Figs. 4 - 6 there is shown a second embodiment of the closure of this invention. That closure is identical in construction to the closure of Figs. 1 - 3, except that the locking member 36 is located interposed between the plug member 30 and the anchor member 32 so that the portion of the filament 34 from the plug member to the anchor member and the portion of the filament from the anchor member back to the plug member each extend through the central opening 62 in the locking member. In this embodiment when the closure is deployed the locking member engages the top 54 of the dome portion of the anchor member, thereby holding the plug 30 further away from the opening 24B in the artery 22 than the embodiment of Figs. 1 - 3, further ensuring that no portion of the plug 30 will enter the artery.

As should be appreciated by those skilled in the art even though the locking member 36 is not located proximally of the plug 30 it nevertheless still prevents the plug 30 from moving away from the anchor 32. In this regard the inward radial compression of the locking washer 36 grasps both portions of the filament extending through its central passageway 62, thereby preventing the filament from moving with respect to the anchor portion. Since the plug is fixedly secured to one end of the filament by the knotted loop 58 the plug 30 is prevented from moving with respect to the anchor 32.

In Figs. 7 - 9 there is shown a third embodiment of the closure of this invention. That closure is identical in construction to the closure of Figs. 1 - 3, except that a separate spacer component 78 is provided interposed between the plug member 30 and the anchor member 32. The spacer member 78 is a disk-like or washer-like member having at least one passageway 80 (Fig. 19) extending therethrough so that the portion of the filament 34 extending from the plug member 30 to the anchor member 32 and the portion of the filament 34 returning from the anchor member to the plug member both extend through the passageway(s) in the component 78. In this embodiment of the

closure, when the closure is deployed the spacer member 78 engages the top 54 of the dome portion 52 of the anchor member 32, thereby holding the plug member 30 further away from the opening 24B in the artery 22 than the embodiment of Figs. 1 - 3, thereby further ensuring that no portion of the plug will enter the artery.

The spacer member 78 is also preferably formed of a resorbable material, such as the polymer used for the anchor member. Moreover, either the spacer member 78, or the locking member 36, or the anchor member 32 may include means, like that described in the aforementioned patent applications, to enable it to be imaged radiographically to facilitate the placement of the closure at the desired situs within the patient's body or to monitor the resorption of the closure.

In Fig. 19 there is shown an alternative closure 100, which while including a locking mechanism for preventing relative movement between the closure components after deployment, does not make use of any locking washer 36 like those described heretofore. In the embodiment of Fig. 19 the closure makes use of the same plug member 30, the same anchor member 32 (except for its passageway 56) and the same spacer member 78 as described above. However, the closure 100 makes use of an alternative embodiment of the filament 34 and a cooperating alternative embodiment of the anchor passageway 56. In particular the filament of the embodiment 100 of Fig. 19 is designated by reference number 34' and comprises a plurality of tooth-like projections 102 at spaced locations therealong. All of tooth-like projections include an inclined surface oriented in the same direction to enable the filament 34' to be slid in only one direction through the transverse passageway 56' in the anchor member 32. Thus, the filament can be thought of as a "one-way" filament. The passageway 56' in the anchor member 30 is similar to that described earlier except that it includes a series of tapered notches 104 adapted to receive therein one or more of the teeth 102 of the filament 34'. In particular, the notches 104 are oriented so that the filament 34 can be slid through the passageway 56' in only one direction. In this regard when moved

in that one direction (shown as right-to-left in Fig. 19) the teeth 102 on the filament 34' can enter into and move out of the notches 104. Thus, when the proximal end of the filament 34' is pulled in the direction of the arrow 106 shown in Fig. 19 (as occurs during the deployment of the closure 100) the plug member 30 is moved toward the anchor member 32 in the same manner as described earlier. However, the one-way filament prevents the plug member from moving away from the anchor member, thereby eliminating the need for a locking washer 36 to hold the plug member in place.

The spacer member 78 is interposed between the plug member 30 and the anchor member 32 operates in the same manner as that described above with reference to Figs. 7 - 9.

As should be appreciated from the foregoing, the deployment of the closure devices of this invention by the instruments of the aforementioned patent applications is easy, quick and reliable. Anchoring is repeatable, safe, and effective to deploy the collagen plug, and hemostasis occurs almost instantaneously, e.g., in 15 seconds or less.

Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

CLAIMS

What is claimed as the invention is:

1. A closure device (20, 100) for sealing a ercutaneous puncture in the wall of a blood vessel (22), said uncture comprising a tract (24A) contiguous with an opening 24B) in a wall of the vessel (22) and extending through tissue verlying said vessel, characterized in that said closure device 20) comprising anchoring means (32), sealing means (30), ilament means (34) having a longitudinal axis, and locking means 36 A/B/C, 56'), said anchoring means (32) being arranged to be rought into engagement with the interior tissue of said vessel 22) contiguous with said opening (24B) and with said sealing eans (30) being located within said tract (24A) remote from said essel (22), said filament means (34, 34') being connected etween said anchoring means (32) and said sealing means (30) so hat said sealing means (30) may be moved in said tract (24A) oward said anchoring means (32) to a puncture sealing position y the application of a pulling force on said filament means (34, 4'), said anchoring means (32) being in engagement with said nterior tissue of said vessel (22) contiguous with said opening 24B) when said sealing means (30) is in said puncture sealing osition, said locking means (36 A/B/C - 56') being actuatable o cooperate with said filament means (34, 102) to hold said nchoring means (32) and said sealing means (30) in said puncture ealing position.

2. The closure device (20) of Claim 1 characterized in hat said locking means (36 A/B/C) comprises a member slidably ounted on said filament means (34), and wherein said locking eans (36 A/B/C) is actuatable by the application of a ompressive force applied thereto parallel to the longitudinal xis of the filament means (34).

3. The closure device (20) of Claim 2 characterized in that said locking means (36 A/B/C) comprises a disk-like member having at least one passageway (e.g., 62) extending therethrough, said filament means (34) extending through said passageway (62), said passageway (62) closing about said filament means (34) extending therethrough upon the application of said compressive force to said locking means (36).

4. The closure device (20, 100) of Claim 1 characterized in that said anchoring means (32), said sealing means (30), said filament means (34, 34'), and said locking means (36 A/B/C, 56') are each formed of a resorbable material.

5. The closure device (20, 100) of Claim 1 additionally comprising spacer means (52, 78) interposed between said sealing means (30) and said anchoring means (32), said spacer means (52, 78) serving to prohibit said sealing means (30) from contacting said vessel wall.

6. The closure device (20, 100) of Claim 5 characterized in that said anchoring means (32), said sealing means (30), said filament means (34, 34'), and said locking means (36 A/B/C, 56') are each formed of a resorbable material.

7. The closure device (20) of Claim 2 characterized in that said locking means (36 A/B/C) is located proximally of said sealing means (30).

8. The closure device (20) of Claim 7 characterized in that said filament means (34) comprises a first end (58) fixedly secured to said sealing means (30), an intermediate portion extending from said sealing means (30) through a passageway (56) in said anchoring means (32) and back to said sealing means (30), and a proximal portion extending along said sealing means (30) through said locking means (36 A/B/C) and out of said percutaneous puncture (24A, 24B), and wherein said locking means (36 A/B/C) when compressed securely engages said proximal portion of said filament means (34) to prevent relative movement between said sealing means (30) and said anchoring means (32).

9. The closure device (20) of Claim 2 characterized in that said locking means (36 A/B/C) is located interposed between said sealing means (30) and said anchoring means (32).

10. The closure device (20) of Claim 9 characterized n that said filament means (34) comprises a first end (58) ixedly secured to said sealing means (30), an intermediate ortion extending from said sealing means (30) through a assageway (36) in said anchoring means (32) and back to said ealing means (30), and a proximal portion extending along said ealing means (30) and out of said percutaneous puncture (24A, 4B), and wherein said locking means (36 A/B/C) when compressed ecurely engages said intermediate portion of said filament means o prevent relative movement between said sealing means (30) and aid anchoring means (30).

11. The closure device (20) of Claim 9 characterized n that said locking means (36 A/B/C) also serves as a spacer rohibiting said sealing means (30) from contacting said vessel all.

12. The closure device (20, 100) of Claim 1 haracterized in that said anchoring means (32) additionally omprises reinforcing means (60) for preventing said anchoring eans from breaking apart.

13. The closure device (100) of Claim 1 characterized n that said locking means (56') comprises a filament engagement ortion (104) configured to enable said filament means (34') to e slid with respect to said anchoring means (32) and said ealing means (30) in a first direction, but precluded from liding with respect to said anchoring means (32) and said ealing means (30) in a second, opposite direction.

14. The closure device (100) of Claim 13 characterized n that said filament means (34') comprises a plurality of rojections (102) extending along at least a portion of the ength of said filament means, and wherein said filament ngagement portion of said locking means comprises a passageway 56') in said anchoring means (32) having at least one notch 104) therein to receive one of said projections (102), said otch (104) being configured to enable said projections to slide herein from said first direction, but preventing any projection rom sliding thereout in said second direction.

15. The closure device (100) of Claim 14 characterized n that said filament means comprises a first end (58A) fixedly ecured to said sealing means (30), an intermediate portion aving said projections (102) thereon and extending from said ealing means (30) through said passageway (56') in said nchoring means (32) and back to said sealing means (30), and a roximal portion extending along said sealing means (30) and out f said percutaneous puncture (24A, 24B).

16. The closure device (100) of Claim 13 characterized n that said anchoring means (32), said sealing means (30), said ilament means (34'), and said locking means (56') are each ormed of a resorbable material.

17. The closure device (100) of Claim 14 further haracterized by spacer means (78) located interposed between aid sealing means (30) and said anchoring means (32), said pacer means (78) serving to prohibit said sealing means from ontacting said vessel wall.

18. The closure device (100) of Claim 17 characterized n that said anchoring means (32), said sealing means (30), said ilament means (34'), said locking means (56'), and said spacer eans (78) are each formed of a resorbable material.

19. The closure device (20, 100) of Claim 1 haracterized in that a portion (e.g., 78, 36 A/B/C, 32) of said losure device (20, 100) comprises a radio-opaque material.

20. A method of sealing a small percutaneous puncture 24A, 24B) in a blood vessel (22) of a living being, said ercutaneous puncture comprising an opening (24B) in said vessel 22) and a tract (24A) contiguous therewith extending through issue overlying said vessel, characterized in that said method omprises providing a closure (20) comprising anchoring means 32), sealing means (30), filament means (34, 34'), and locking eans (36 A/B/C, 56'), movably coupling said anchor means (32), aid sealing means (30), and said locking means (36 A/B/C, 56') ogether by said filament means (34, 34'), inserting said nchoring means (32) within said vessel (22) in engagement with ne interior of said vessel (22) contiguous with said opening 24B) and with said sealing means (30) within said tract so that

said sealing means is located remote from said vessel, operating said filament means to move said sealing means toward said anchoring means to seal said percutaneous puncture, and actuating said locking means to cause said locking means to engage said filament means in such a manner that said sealing means and said anchoring means are prevented from moving away from each other.

21. The method of Claim 20 characterized in that said locking means (36 A/B/C) comprises a member (36 A/B/C) slidably mounted on said filament means (34) and located in the puncture tract (24A), and wherein actuating of said locking means (36 A/B/C) comprises applying a compressive force to said locking member in a direction parallel to the longitudinal axis of said filament means (34) to cause said locking member (36 A/B/C) to engage said filament means (34), whereupon said sealing means (30) and said anchoring means (32) are prevented from moving relative to each other.

22. The method of Claim 20 characterized in that said locking means (36 A/B/C, 56') comprises a filament engagement portion (62, 104) configured to enable said filament means (34, 34') to be slid with respect to said anchoring means (32) and said sealing means (30) in a first direction, but precluded from sliding with respect to said anchoring means (32) and said sealing means (30) in a second, opposite direction, and wherein actuating of said locking means (36 A/B/C, 56') comprises pulling on said filament means (34, 34') to cause said sealing means (30) to move toward said anchoring means (32) in said first direction.

23. The method of Claim 20 further characterized by the step of providing spacer means (78) interposed between said anchoring means (32) and said sealing means (30) to prevent said sealing means (30) from gaining ingress into said vessel (22) via said opening (22B).

24. The method of Claim 21 further characterized by the step of providing spacer means (78) interposed between said anchoring means (32) and said sealing means (30) to prevent said sealing means (30) from gaining ingress into said vessel (22) via said opening (22B).

25. The method of Claim 22 further characterized by the step of providing spacer means (78) interposed between said anchoring means (32) and said sealing means (30) to prevent said sealing means (30) from gaining ingress into said vessel (22) via said opening (22B).

FIG. 1

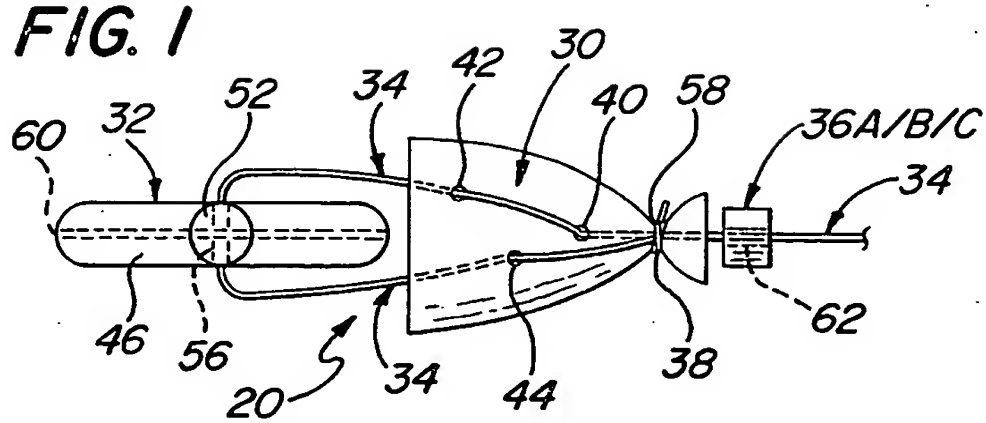


FIG. 2

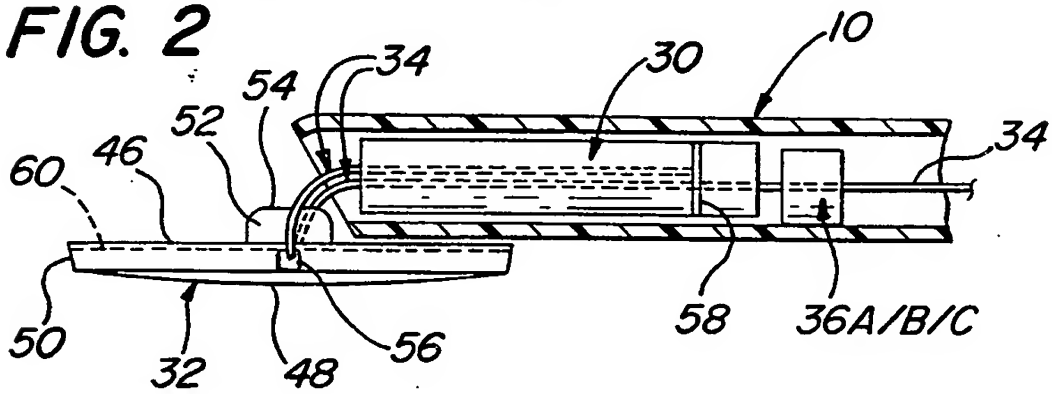


FIG. 3

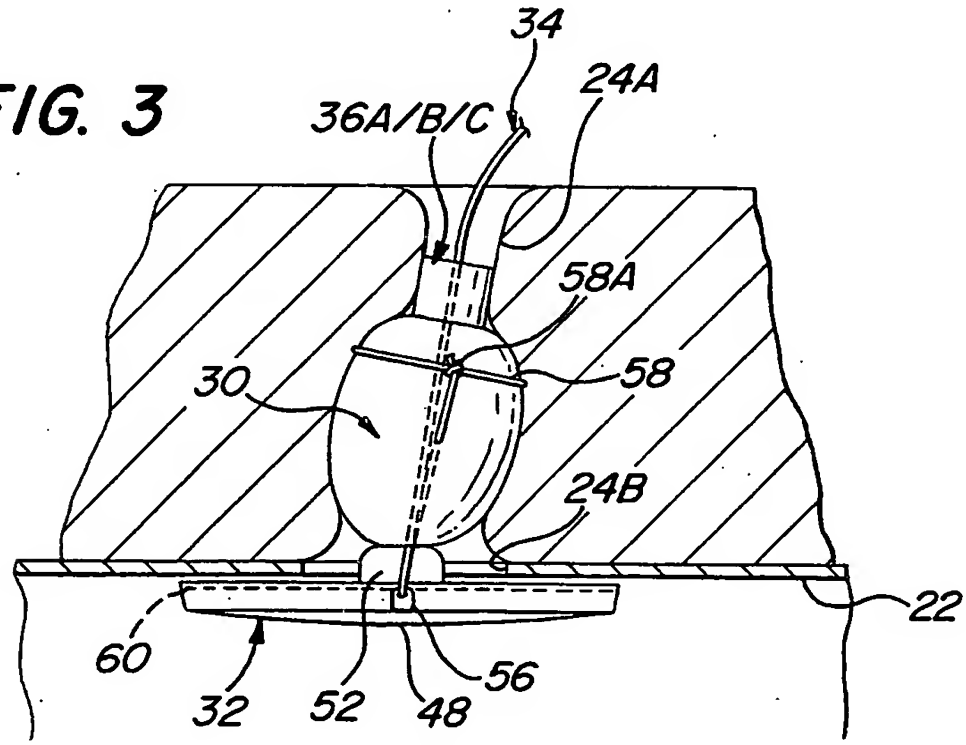


FIG. 4

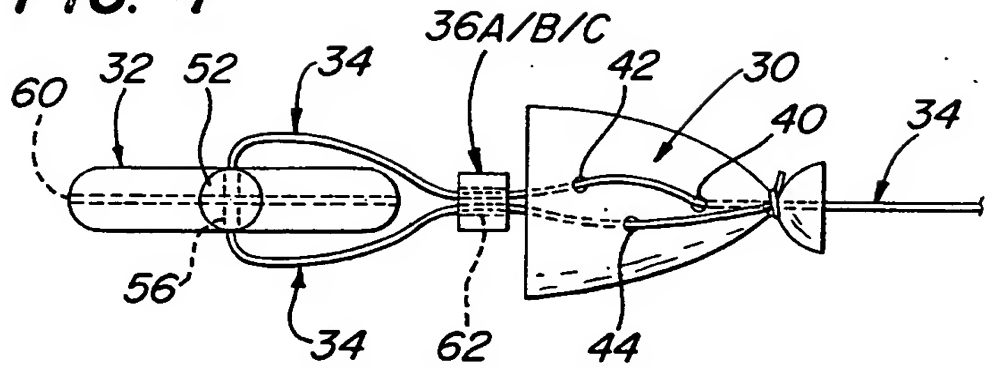


FIG. 5

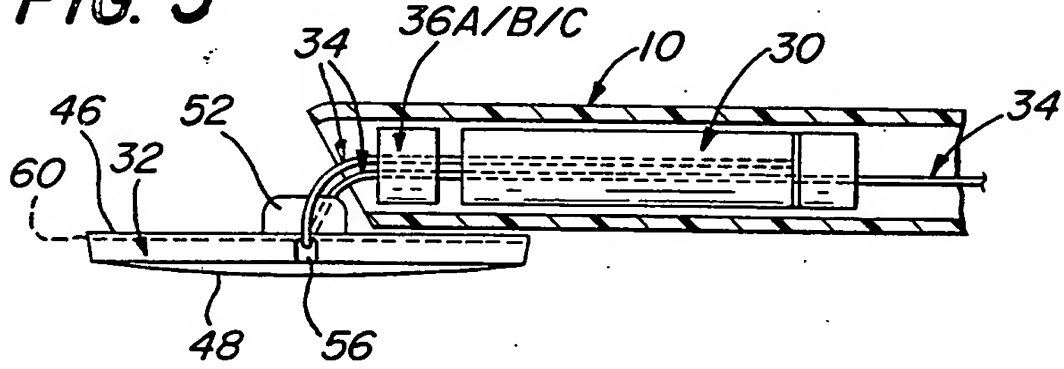


FIG. 6

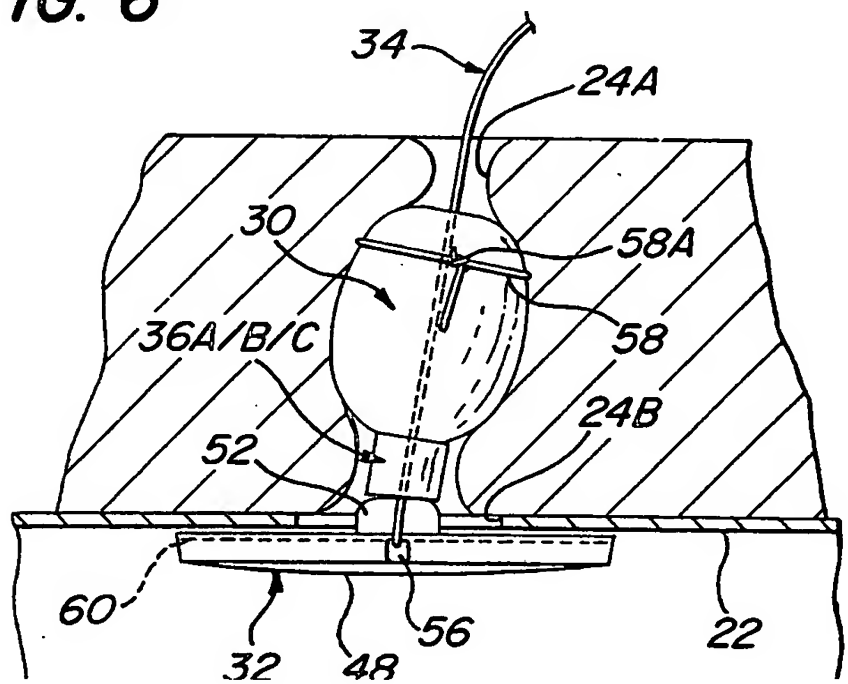


FIG. 7

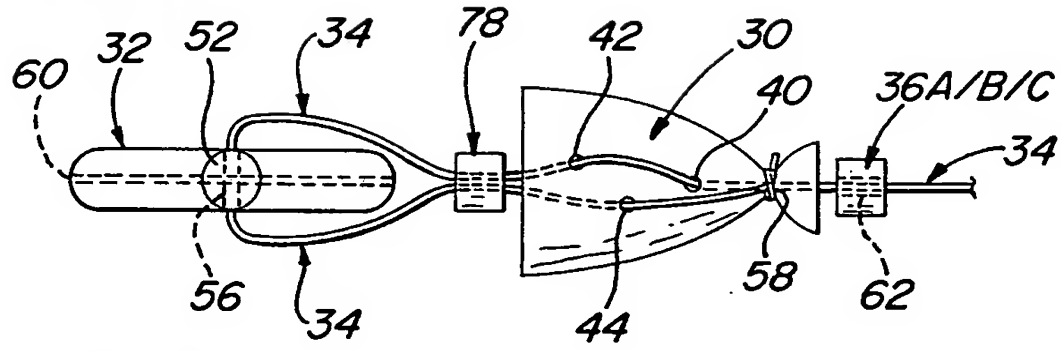


FIG. 8

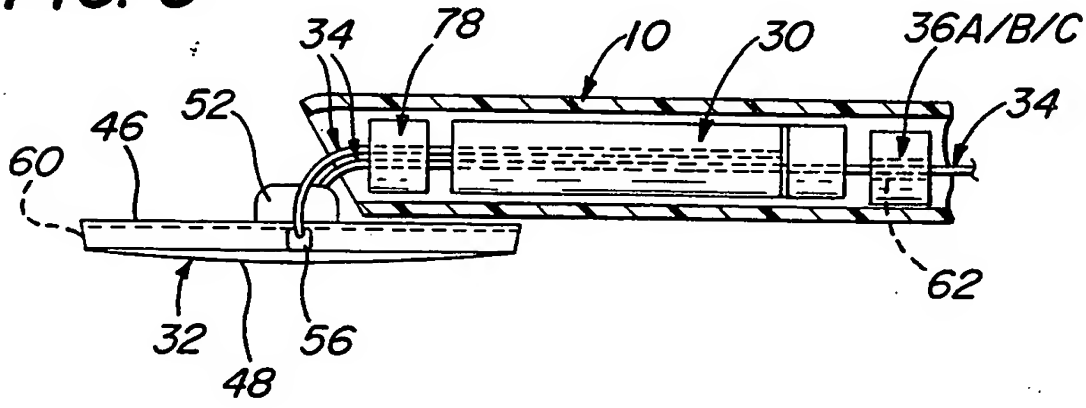


FIG. 9

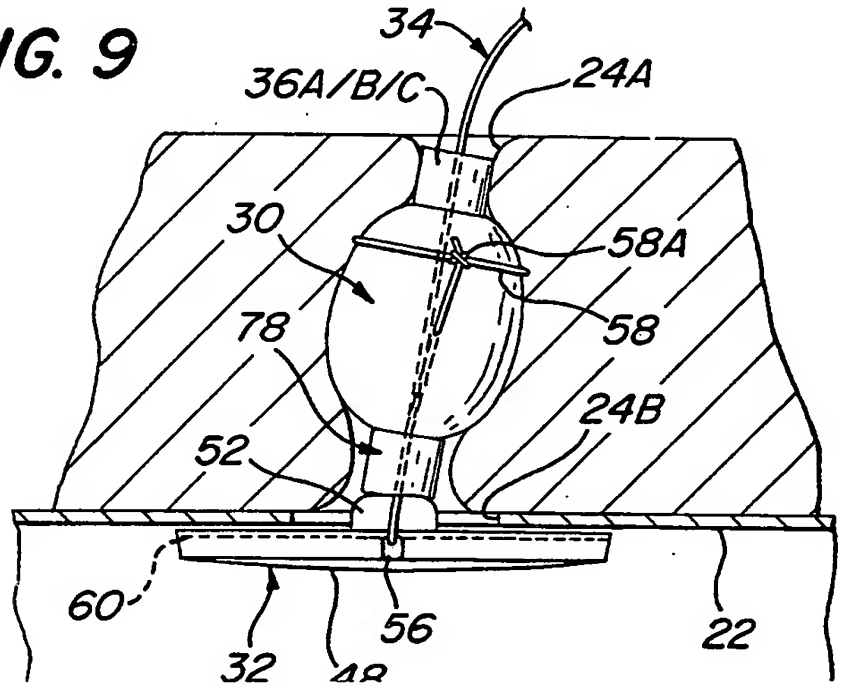


FIG. 10

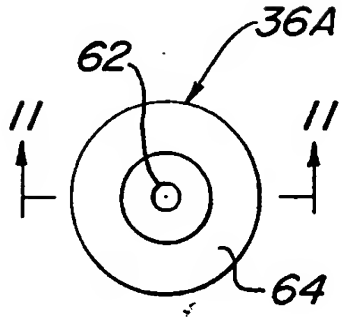


FIG. 11

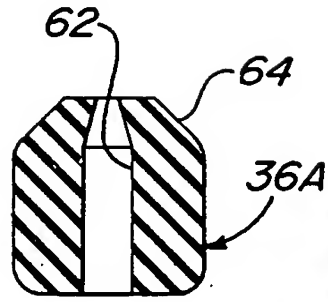


FIG. 12

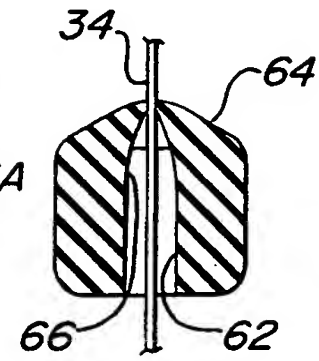


FIG. 13

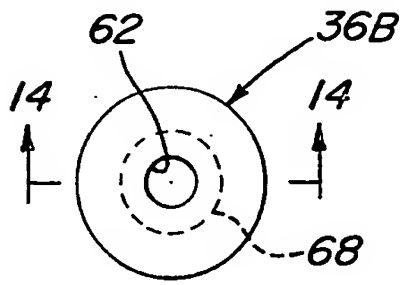


FIG. 14

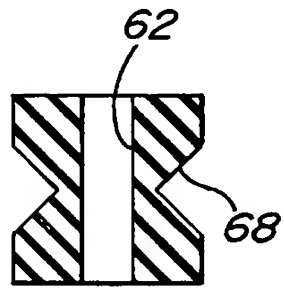


FIG. 15

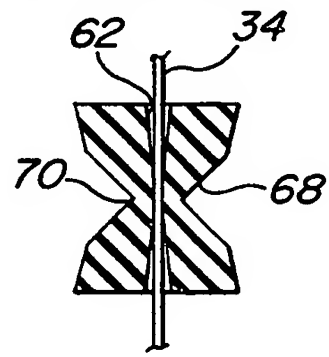


FIG. 16

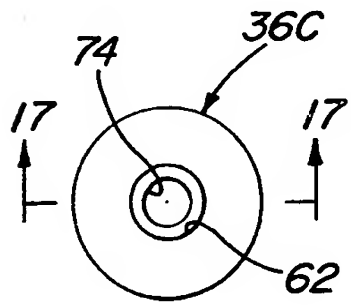


FIG. 17

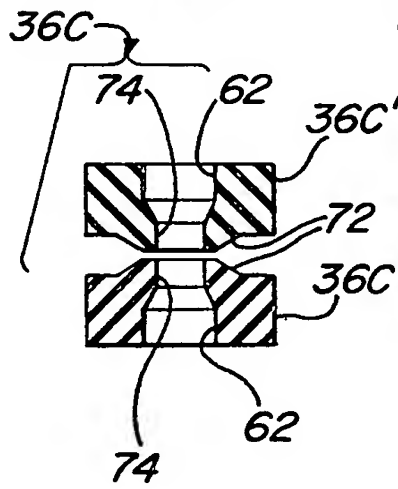


FIG. 18

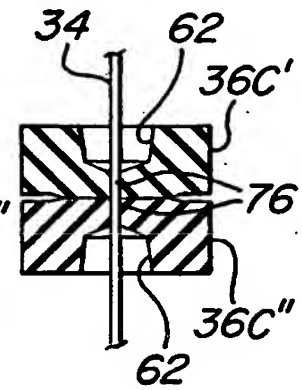
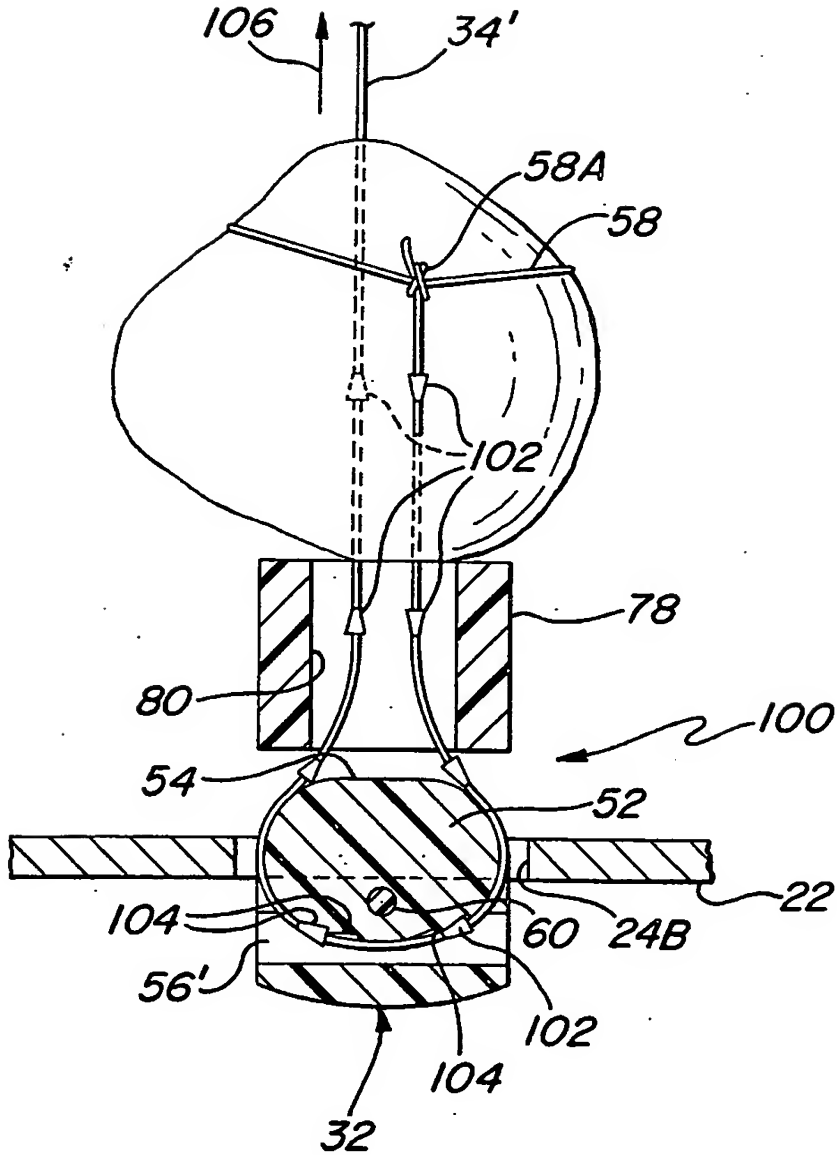


FIG. 19



INTERNATIONAL SEARCH REPORT

Inte .onal Application No
PCT/US 94/06324

CLASSIFICATION OF SUBJECT MATTER
PC 5 A61B17/00

cording to International Patent Classification (IPC) or to both national classification and IPC

FIELDS SEARCHED

nimum documentation searched (classification system followed by classification symbols)
)C 5 A61B

cumentation searched other than minimum documentation to the extent that such documents are included in the fields searched

ctronic data base consulted during the international search (name of data base and, where practical, search terms used)

)OCUMENTS CONSIDERED TO BE RELEVANT

:gory *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	WO,A,93 08746 (KENSEY NASH CORP.) 13 May 1993 cited in the application see claims 1,27	1-19
	WO,A,90 14796 (MUIJS VAN DE MOER) 13 December 1990 see page 5, line 7 - line 16; figure 6	1-12
	WO,A,92 06639 (EBERBACH) 30 April 1992 see page 13, line 1 - line 3	13-19
	US,A,4 744 364 (KENSEY) 17 May 1988 see column 5, line 28 - line 35	1

Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

:cial categories of cited documents :

document defining the general state of the art which is not considered to be of particular relevance

earlier document but published on or after the international filing date

document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

document referring to an oral disclosure, use, exhibition or other means

document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

of the actual completion of the international search	Date of mailing of the international search report
26 October 1994	11. 11. 94
e and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk	Authorized officer

INTERNATIONAL SEARCH REPORT

Inte. ional application No.
PCT/US94/06324

Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

rnational search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

Claims Nos.: 20-25.
because they relate to subject matter not required to be searched by this Authority, namely:

Method for treatment of the body by surgery.
Rule 39.1 (iv) PCT.

Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

rnational Searching Authority found multiple inventions in this international application, as follows:

As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .onal Application No
PCT/US 94/06324

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9308746	13-05-93	US-A-	5222974	29-06-93
		US-A-	5282827	01-02-94
		AU-A-	3128993	07-06-93
WO-A-9014796	13-12-90	NL-A-	8901350	17-12-90
		AU-A-	5823590	07-01-91
		EP-A-	0474752	18-03-92
		JP-T-	4505721	08-10-92
WO-A-9206639	30-04-92	US-A-	5141515	25-08-92
		AU-A-	8934791	20-05-92
		CA-A-	2079222	12-04-92
		EP-A-	0519022	23-12-92
		US-A-	5116357	26-05-92
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		US-A-	4852568	01-08-89
		US-A-	4890612	02-01-90